Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of Trazosin on sweating of Sertralin side effect in depressed patients: a double blind clinical trial study

Protocol summary

Summary

The aim of this study is to survey the effect of trazosin on sertralin inducing sweating. In this double blind clinical trial, 134 depressed patients (with DSM IV-TR criteria) on the treatment with sertralin who suffered from sweating were enrolled and randomly assigned to receive 1mg trazosin in bed time or similar amount of placebo. Two weeks later, intensity of sweating was recorded at the baseline and after two weeks after the intervention and compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138905064459N1**
Registration date: **2010-10-23, 1389/08/01**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2010-10-23, 1389/08/01

Registrant information

Name

Ali Ghaleiha

Name of organization / entity

Hamadan University of Medical Sciences and Health Services

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Deputy Dean of Research, Hamadan University of Medical Sciences

Expected recruitment start date

2009-04-04, 1388/01/15

Expected recruitment end date

2009-10-07, 1388/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Trazosin on sweating of Sertralin side effect in depressed patients: a double blind clinical trial study

Public title

Effect of Trazosin on sweating of Sertralin side effect in depressed patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: The patients who referred to the psychology clinic of Farshchian Hospital or to the private clinic of the psychologists of Hamadan city and were depressed based on the DSM IV-TR criteria, had sweating side effect due to the consumption of Sertralin Exclusion criteria: not willing to participate in each stage of the experiment, presence of systemic disease such as hypertension, diabetes, presence of other psychological disorder, using other medicine or suffering from the side effect of Trazosin or placebo like orthostatic hypotension, vertigo, headache

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **134**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research ethics committee of Hamadan University of Medical Sciences

Street address

Research ethics committee, Deputy Dean of Research, Hamadan University of Medical Sciences

City

Hamadan

Postal code

65178518

Approval date

2008-07-27, 1387/05/06

Ethics committee reference number

56578/9/35/16/پ

Health conditions studied

1

Description of health condition studied

Depressive Disorder

ICD-10 code

F32

ICD-10 code description

Depressive episode

Primary outcomes

1

Description

sweating

Timepoint

Baseline and 2 weeks after the intervention

Method of measurement

visual analog scale

Secondary outcomes

1

Description

headache

Timepoint

daily

Method of measurement

case talking

2

Description

sexual insufficiency

Timepoint

daily

Method of measurement

physical axam and case talking

3

Description

orthostatic hypotension

Timepoint

Daily

Method of measurement

physical axam and case talking

4

Description

palpitation

Timepoint

daily

Method of measurement

physical axam and case talking

5

Description

vertigo

Timepoint

Daily

Method of measurement

physical axam and case talking

6

Description

nasal cogestion

Timepoint

Daily

Method of measurement

physical axam and case talking

Intervention groups

1

Description

control: placebo, tablet 1mg in bed time, for two weeks

Category

Placebo

2

Description
Intervention: Trazosin, Tablet 1m in bed time, for two weeks
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Behavioral disorders and substance abuse research center of Hamadan University of Medical Sciences
Full name of responsible person
Ali ghaleiha, Psychiatrist, Assistant Professor
Street address
Farshchian hospital, behavioral disorders and substance abuse research center
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Hamadan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Deputy Dean of Research, Hamadan University of Medical Sciences
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Ali Ghaleiha
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Deputy Dean of Research, Hamadan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty